PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
GREGORY L. MAYBACK
FELDMAN GALE, P.A.
MIAMI CENTER, 19TH FLOOR
201 SOUTH BISCAYNE BLVD
MIAMI, FL 33131-4332

PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	26 JUL 2006
Applicant's or agent's file reference GLM-1042 PCT	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US04/28530	02 September 2004 (02.09.2004)	03 September 2003 (03.09.2003)

Applicant

BOLTON MEDICAL INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Brian Pellegrino Telephone No. 571-272-4300

Form PCT/IPEA/416 (January 2004)

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference GLM-1042 PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US04/28530	International filing date *(day/month/year)* 02 September 2004 (02.09.2004)	Priority date *(day/month/year)* 03 September 2003 (03.09.2003)
International Patent Classification (IPC) or national classification and IPC IPC: **A61F 2/06**(2006.01),**2/84**(2006.01) USPC: 623/1.11,1.13		
Applicant BOLTON MEDICAL INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of ___ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01 April 2005 (01.04.2005)	18 June 2006 (18.06.2006)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer /Brian Pellegrino/ Telephone No. 571-272-4300

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/28530

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:
pages 1-46 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the claims:
pages 47-76 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the drawings:
pages 1-24 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/28530

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO
Inventive Step (IS)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO
Industrial Applicability (IA)	Claims Please See Continuation Sheet	YES
	Claims Please See Continuation Sheet	NO

2. Citations and Explanations (Rule 70.7)

Please See Continuation Sheet

Claims 1,2,6,15-17,20,21,24,43,46-48,87-90,93,94,96 lack novelty under PCT Article 33(2) as being anticipated by Lenker et al. Lenker discloses (Fig. 1) a tubular graft body 20 and a structural framework with at least two stents 14. Fig. 4 shows the vascular repair device has a curved longitudinal support member 42 connected to the graft body independent of the stents. Lenker also discloses the support or runner is made of nitinol or stainless steel, col. 8, lines 27-29,49. Fig. 33 shows a delivery system with a control handle and a control assembly 34 with a hollow catheter or cover 32 connected to the control handle. It can be seen there is also a delivery assembly disposed in the catheter and Fig. 27 shows a shaft 44 having a lumen for a guidewire within the lumen of the catheter, see also col. 7, line 27. The guidewire lumen is curved when inserted in a curved vessel as is shown to be curved in Fig. 27. Lenker additionally discloses the implantation site is a curved portion of a branch vessel off the aorta, col. 9, lines 46-48.

Claims 91,92 lack an inventive step under PCT Article 33(3) as being obvious over Lenker et al. Lenker et al. is explained supra. However, Lenker fails to disclose the guidewire lumen is made of metal. The use of metal, such as stainless steil for guidwire lumens is well known in the art. It would have been an obvious expedient to use steel for the guidewire lumen with the delivery system of Lenker et al. such that it provide a protective lumen to prevent the guidewire from puncturing any portion of the vessel.

Claims 1,4,7-10,14,16,17,41 lack novelty under PCT Article 33(2) as being anticipated by Hijlkema. Fig. 2B shows that the vascular repair device has at least two stents 12i, 12ii and a pre-curved longitudinal support member 21'I connected to the stents. Hijlkema also discloses the device includes a tubular graft body, col. 5, lines 12-14. Fig. 3 shows the support member can extend along the stent and can be construed to be a partial helix. It can be seen that the support members are shorter than the structural framework.

Claim 3 lacks an inventive step under PCT Article 33(3) as being obvious over Hijlkema. Hijlkema is explained supra. However, Hijlkema fails to disclose the support member as being S-shaped. S-shaped "support members" are well known in the art and provide more flexibility to the stent. It would have been an obvious expedient to incorporate an S-shape in the support member of Hijlkema such that it permits the device to more easily move through tortuous vessels.

Claims 1,20-26,28-40,42 lack novelty under PCT Article 33(2) as being anticipated by Hartley et al. Fig. 1 shows a vascular repair device with a tubular graft body 5 with a structural framework of at least two stents 7,8 connected to the graft body. Fig. 3 shows the device having what can be construed as a curved longitudinal support member 16. Regarding claim 20, Hartley's Fig. 2 can also be interpreted to have at least an outer stent 1 and an inner stent 8 separated from one another. Regarding claim 26, it appears that the support member 16 connected to the graft body does not touch the stents, Fig. 4. With respect to claims 30 and 39, Fig. 2 shows stent 7 having a periodically changing shape with distal apices having a smaller radii of curvature than the proximal apices.

Claims 68-77,83,84 lack novelty under PCT Article 33(2) as being anticipated by Fischell et al. Fischell discloses implanting a stent in a vessel using radiopaque markers to view the device while inserting it in the patient, col. 1, lines 65-67. Fig. 2 shows a pair of opposing radiopaque markers 15 along the longitudinal axis of the stent. Fischell also discloses aligning the device by orienting the device along the longitudinal axis by rotating the device until viewing the markers, col. 3, lines 23-29. The cross-section shown in Fig. 2 can be construed to be D-shaped or oval.

Claims 51-70,73,77,83-86 lack novelty under PCT Article 33(2) as being anticipated by Marcade. Marcade discloses (Fig. 2) a vascular repair device with a tubular graft body 112 with a structural framework 162 connected to the body and a pair of radiopaque markers 148 connected to the graft body. It can be construed that the markers are hemispherical since they are on the tubular graft surface. Marcade discloses the markers are disposed about the circumference such that there are markers opposing one another on opposite sides of the graft, col. 10, lines 65-67. Marcade discloses multiple stents can be used with the graft, col. 16, lines 4-7. Marcade also discloses methods of deploying the graft device using the markers to align it properly within the vessel, col. 16, lines 46-65.

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claims 96-159 are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: these claims should be renumbered because there was no claim 95.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V.1. Reasoned Statements:
The opinion as to Novelty was positive (Yes)with respect to claims 3,5,11-13,18,19,27,44,45,49,50,78-82,91,92,95,97-122,126-132,137,139-141,145-149,154,156-158
The opinion as to Novelty was negative (No) with respect to claims 1,2,4,6-10,14-17,20-26,28-43,46-48,51-77,83-90,93,94,96,123-125,133-136,138,142-144,150-153,155,159
The opinion as to Inventive Step was positive (Yes)with respect to claims 5,11-13,18,19,27,44,45,49,50,78-82,95,97-122,126-132,137,139-141,145-149,154,156-158
The opinion as to Inventive Step was negative(NO) with respect to claims 1-4,6-10,14-17,20-26,28-43,46-48,51-77,83-94,96,123-125,133-136,138,142-144,150-153,155,159
The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-159
The opinion as to Industrial Applicability was negative(NO) with respect to claims NONE

V. 2. Citations and Explanations:

Claims 123-125,133-136,138,142-144,150-153,155,159 lack novelty under PCT Article 33(2) as being anticipated by Langberg et al. Langberg et al. disclose a method of delivering a prosthesis to a curved vessel using a guidewire, col. 10, lines 41-44. Fig. 3 shows a guidewire lumen having a curved distal portion 80. Figs. 1 and 6 show the curved implantation site. Langberg additionally discloses that the surgeon monitors the delivery of the prosthesis, col. 12, lines 58-60.

Claims 5,11-13,18,19,27,44,45,49,50,78-82,95,97-122,126-132,137,139-141,145-149,154,156-158 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the combination of features in each of the claims.

Claims 1,2,6,15-17,20,21,24,43,46-48,87-90,93,94,96 lack novelty under PCT Article 33(2) as being anticipated by Lenker et al. Lenker discloses (Fig. 1) a tubular graft body 20 and a structural framework with at least two stents 14. Fig. 4 shows the vascular repair device has a curved longitudinal support member 42 connected to the graft body independent of the stents. Lenker also discloses the support or runner is made of nitinol or stainless steel, col. 8, lines 27-29,49. Fig. 33 shows a delivery system with a control handle and a control assembly 34 with a hollow catheter or cover 32 connected to the control handle. It can be seen there is also a delivery assembly disposed in the catheter and Fig. 27 shows a shaft 44 having a lumen for a guidewire within the lumen of the catheter, see also col. 7, line 27. The guidewire lumen is curved when inserted in a curved vessel as is shown to be curved in Fig. 27. Lenker additionally discloses the implantation site is a curved portion of a branch vessel off the aorta, col. 9, lines 46-48.

Supplemental Box

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Continuation of:

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The opinion as to Novelty was negative (No) with respect to claims 1,2,4,6-10,14-17,20-26,28-43,46-48,51-77,83-90,93,94,96,123-125,133-136,138,142-144,15-153,155,159
The opinion as to Inventive Step was positive (Yes)with respect to claims 5,11-13,18,19,27,44,45,49,50,78-82,95,97-122,126-132,137,139-141,145-149,154,156-158
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The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-159
The opinion as to Industrial Applicability was negative(NO) with respect to claims NONE